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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/635,665

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Hiraku Murayama

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EXAMINER

HOEKSTRA, JEFFREY GERBEN

ART UNIT

PAPER NUMBER

3736

NOTIFICATION DATE

DELIVERY MODE

08/11/2008

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

ADIPFDD@bipc.com

<b>Office Action Summary</b>	<b>Application No.</b> 10/635,665	<b>Applicant(s)</b> MURAYAMA ET AL.	
	<b>Examiner</b> JEFFREY G. HOEKSTRA	<b>Art Unit</b> 3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 12 May 2008.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-6, 12-21, 23-28, 30 and 32-35 is/are pending in the application.
- 4a) Of the above claim(s) 4-6 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-3, 12-21, 23-28, 30 and 32-35 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 07 August 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Notice of Amendment***

1. In response to the amendment filed on 05/12/2008, amended claim(s) 1-3, 12, 20, 21, 24, and 28 and canceled claim(s) 22, 29, and 31 is/are acknowledged. The previous rejections of claims 1-3, 12-21, 23-28, 30, and 32-35 are withdrawn. The following new and reiterated grounds of rejection are set forth:

### ***Claim Rejections - 35 USC § 103***

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
3. Claims 1-3, 12-15, 16-18, 23, and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Uchino et al. (US 6,001,068, hereinafter Uchino) in view of Jafari et al. (US 6,702,762 B2, hereinafter Jafari).
4. Uchino discloses a guidewire, comprising:
- a distally disposed reshapeable and non-superelastic metallic first wire comprising a coil (112,66,81) (the gold or platinum positively recited in column 6 lines 15-19, column 12 lines 29-33, column 15 lines 36-42) having a proximal end (the right end as best seen in Figures 1 and 9-19) and being capable of being plastically deformed to maintain a desired shape;
  - an intermediately disposed pseudo-elastic alloy second wire (A,61) (column 3 line 46 – column 4 line 6) having a smaller elastic modulus than the first wire and a distal end (the left end as best seen in Figures 1 and 9-19); and

- a proximally disposed third wire (B,62) (column 4 lines 7-25) having a larger elastic modulus than the second wire (the stainless steel for example positively recited in column 4 lines 7-25);
- wherein said first and second wires have a common longitudinal axis, are coaxial, and are welded at a welded portion at the distal and proximal ends by spot or butt-resistance welding (column 7 lines 19-67 and column 8 lines 16-22) (as best seen in Figure 12) of the end faces of the two wires in a nearly perpendicular orientation with respect to the longitudinal axis,
- wherein the second and third wire are joined to each other by spot or butt-resistance welding (column 7 lines 19-67 and column 8 lines 16-22) (as best seen in Figures 1-4, 9-15, and 17-19), and
- wherein the guidewire has a taper extending from the proximal end to the distal end (as best seen in Figures 9, 14, and 17).

5. Uchino discloses the claimed guidewire, as set forth above, except for expressly disclosing the first wire is not a coil, is configured to be plastically deformed to a desired shape and maintained in the desired shape upon being bent in the desired shape by a user, and ranges in length from 10 to 1,000 mm.

6. Jafari teaches a guidewire (20) comprising *inter alia*: a distally disposed first wire (70) having a proximal end (the left end of element 70 as best seen in Figure 1) welded to a distal end (the right end of element 30 as best seen in Figure 1) of a second wire (30) at a welded portion (82) (column 3 lines 32-63), wherein said first wire is made from a reshapeable and non-superelastic metal material (column 3 lines 32-63) and said

second wire is made from a pseudo-elastic metallic alloy (the Nitinol positively recited in column 3 lines 32-63), and wherein said first wire is not a coil (as best seen in Figure 1), is configured to be plastically deformed to a desired shape and maintained in the desired shape upon being bent in the desired shape by a user (column 3 lines 49-52), and ranges in length from 10 to 1,000 mm (column 6 lines 23-67).

7. Thus for claims 1-3, 12-15, 16-18, 23, and 28, all the claimed elements were known in the prior art and one skilled in the art could have combined the elements as claimed by known methods with no change in their respective functions, and the combination would have yielded predictable results to one of ordinary skill in the art at the time of the invention. All of the component parts are known in Uchino and Jafari. The only difference is the combination of the component parts into a single device. Thus, it would have been obvious to one having ordinary skill in the art at the time of the invention to combine the components as taught by Uchino with the components as taught by Jafari to achieve the predictable results of configuring the mechanical properties (i.e. flexibility, elastic modulus, etc...) of a guidewire for navigating tortuous vasculature.

8. Claims 19-21, 24-27, 30, and 32-35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Uchino in view of Jafari and in further view of Palermo et al. (US 5,769,796, hereinafter Palermo).

9. Uchino in view of Jafari discloses the claimed guidewire, as set forth above, except for expressly disclosing configuring the guidewire with a spiral coil covering at

least the distal end portion of the first wire, wherein the welded portion between first and second wires is located distal or proximal the proximal end of the spiral coil, wherein the coil covers the welded portion and is spaced outwardly away from the welded portion, wherein at least a portion of the spiral coil is located distally beyond a distal end of the welded portion, wherein the spiral coil possess an axial extent greater than an axial extent of welded portion, wherein the spiral coil is fixed at an intermediate portion to the first wire with a first fixing material, and wherein a second fixing material fixes the distal end portion of the spiral coil to the first wire.

10. Palermo teaches configuring a guidewire (100) with a spiral coil of wire (112) covering at least the distal end portion of a first wire (126), wherein a welded portion (128) between the first (126) and a second wire (122) is located distal or proximal the proximal end of the spiral coil (as best seen in Figures 5A and 5B), wherein the coil covers the welded portion and is spaced outwardly away from the welded portion (as best seen in Figures 5A and 5B), wherein at least a portion of the spiral coil is located distally beyond a distal end of the welded portion (as best seen in Figures 5A and 5B), wherein the spiral coil possess an axial extent greater than an axial extent of welded portion (as best seen in Figures 5A and 5B), wherein the spiral coil is fixed at an intermediate portion to the first wire with a first fixing material (128), and wherein a second fixing material (110) fixes the distal end portion of the spiral coil to the first wire.

11. Thus for claims 19-21, 24-27, 30, and 32-35, all the claimed elements were known in the prior art and one skilled in the art could have combined the elements as claimed by known methods with no change in their respective functions, and the

combination would have yielded predictable results to one of ordinary skill in the art at the time of the invention. All of the component parts are known in Uchino in view of Jafari and Palermo. The only difference is the combination of the component parts into a single device. Thus, it would have been obvious to one having ordinary skill in the art at the time of the invention to combine the components as taught by Uchino in view of Jafari with the components as taught by Palermo to achieve the predictable results of configuring the mechanical properties (i.e. flexibility, elastic modulus, etc...) of a guidewire for navigating tortuous vasculature.

### ***Response to Arguments***

12. Applicant's arguments with respect to claims 1-3, 12-21, 23-28, 30, and 32-35 have been considered but are moot in view of the new ground(s) of rejection.

### ***Conclusion***

13. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JEFFREY G. HOEKSTRA whose telephone number is (571)272-7232. The examiner can normally be reached on Monday through Friday 8am to 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571)272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/J.H./  
Jeff Hoekstra  
Examiner, Art Unit 3736

/Max Hindenburg/  
Supervisory Patent Examiner, Art Unit 3736